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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/763,400  | 01/23/2004  | Glenn R. Frank       | DI-1-3              | 4564             |
| 26949   | 7590        | 12/09/2004           | EXAMINER            |                  |
| HESKA CORPORATION<br>INTELLECTUAL PROPERTY DEPT.<br>1613 PROSPECT PARKWAY<br>FORT COLLINS, CO 80525 |             |                      | SWARTZ, RODNEY P    |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1645                |                  |

DATE MAILED: 12/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/763,400

Applicant(s)

FRANK ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 106-115 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 106-115 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6-25-04, 4-19-04
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicants' Preliminary Amendment, received 25 June 2004, is acknowledged. Claims 1-105 have been canceled. New claims 106-115 have been added.
2. Claims 106-115 are pending and under consideration.

### **Drawings**

3. The drawings submitted are declared informal. The drawings are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.
4. Figure 1 is objected to because the description in the specification, page 36, lines 1-3, recites closed circles (Human Fc R) and open circles (D9). However, the figure shows closed circles for D9 and closed squares for HuFcERI. Correction is required.
5. Figures 5 and 6 are objected to because the description in the specification, pages 40 and 41 recite that 10 groups are depicted in Figures 5 and 6, but group 9, heat-inactivated heartworm pool sera is missing from both figures. Correction is required.

### **Specification**

6. The disclosure is objected to because of the following informalities:  
Page 6, lines 13-16, contains duplicate sentences ; lines 10-18 defines terminology  
abhorrent to normal use, i.e., defining the words "a" and "an" to mean  
both plural and singular.  
Page 10, the sentence beginning on line 14 is unclear, words appear to be missing.  
Page 13, line 1, there needs to be a period following "antigen".  
Page 13, line 23, should be amended to indicate that U.S. Pat. Appl. 08/715,628 is now  
Pat. No. 6,391,569.

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Page 14, line 3, "posses" should be "possess"

Page 38, line 16, "Immitis" should be "immitis",

Page 41, line 16, "clarafied" should be "clarified"

Page 45, line 2, "anit-canine" should be "anti-canine".

Appropriate correction is required.

### **Claim Rejections - 35 USC § 103**

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 106-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kinet (U.S. Pat. No. 5,770,396) in view of Zuk et al (U.S. Pat. No. 4,208,479).

The instant claims are drawn to labelled, isolated human Fc epsilon receptor alpha chain protein which comprises an amino acid sequence from a selected list of sequence identifiers.

Kinet teaches the isolated human Fc epsilon receptor alpha chain protein comprising the listed amino acid sequences (Abstract; sequence 11; Figure 2). However, Kinet does not teach labelling the protein with detectable markers.

Zuk et al teach the general principles by which receptors may be labelled by a variety of markers for use in immunoassays for detection of immunoglobulin E (Abstract; col. 3, lines 31-39; col. 7, line 9 to col. 8, line 53; col. 15, line 25 to col. 26, line 18).

Thus, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to label the isolated receptor of Kinet utilizing the procedures of Zuk et al in order to provide a reagent for immunoassay of human IgE.

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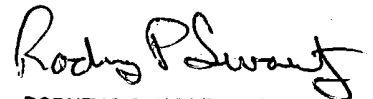
### Conclusion

9. No claims are allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER

Art Unit 1645

December 8, 2004